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## **Treatment of TASC C D lesions with DCB**

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# **Lutonix**

## **SFA Long Lesion Study**

### **Two Year Results**

A Prospective, Multicenter, Single-Arm Trial with the  
Lutonix<sup>®</sup> Drug Coated Balloon for Treatment of  
Long Lesions in Femoropopliteal Arteries

M. Banyai ,MD



# Disclosure

**M. Banyai, M.D.**

I have the following potential conflicts of interest to report:

X Consulting

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

Other(s)

I do not have any potential conflict of interest



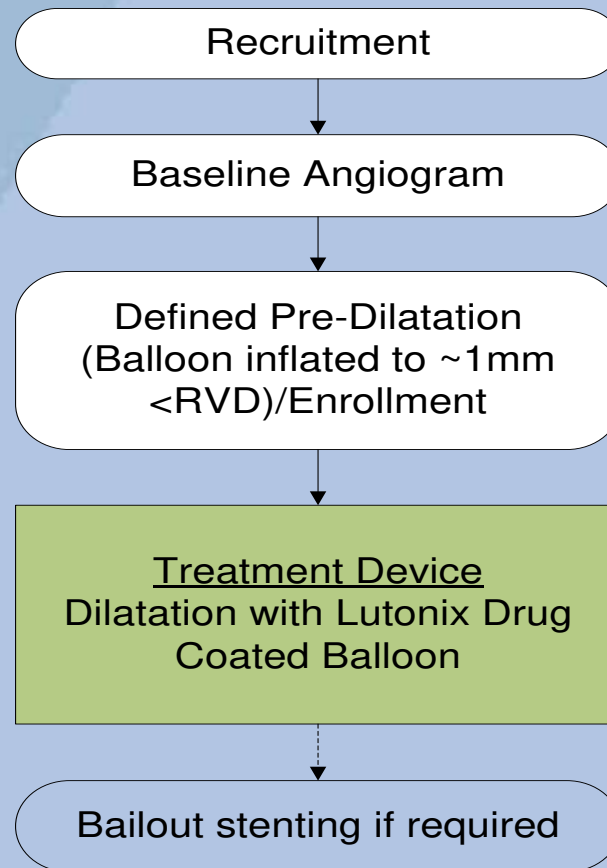
# Conflicts of Interest

Consultant to Bard

# Study Design

<b>Study Design</b>	Single Arm, Prospective, EU, Multicenter, Safety and Effectiveness Study
<b>Objective</b>	To investigate the safety, clinical use, and outcomes of the Lutonix Drug Coated Balloon for treatment of Long Lesions ( $\geq 14$ cm) in the femoropopliteal artery
<b>Number of patients/sites</b>	118 DCB patients – 14 sites
<b>Key Inclusion Criteria</b>	Rutherford Class: 2-4, TASC II Class C or D Lesions, $\geq 70\%$ stenosis lesion, lesion length $\geq 14$ cm, vessel diameter of 4-7 mm
<b>Key Exclusion Criteria</b>	Life expectancy $< 1$ yr., prior vascular surgery of the index limb, target lesion previously stented, inadequate distal outflow ( $> 50\%$ stenosis of distal popliteal or all three tibial vessels)

# Single-Arm Study - Levant 2 Design



# Patient Follow-Up

EVENT	Pre-Procedure (Baseline)	Procedure	Post-Procedure	1 Month	6 Month	12 Month	24 Month	36 Month	Repeat Angio/Revasc
Inclusion/Exclusion Criteria	√	√							
Informed Consent	√								
Medical History	√								
Physical Exam	√		√	√	√	√	√		√
Medication Compliance	√			√	√	√	√	√	√
Resting ABI	√		√	√	√	√	√		√
Rutherford Classification	√				√	√	√		√
WIQ & EQ5D Questionnaires	√				√	√	√		
Angiogram		√							√
Adverse Event Monitoring		√	√	√	√	√	√	√	√
Duplex Ultrasound			√		√	√	√		

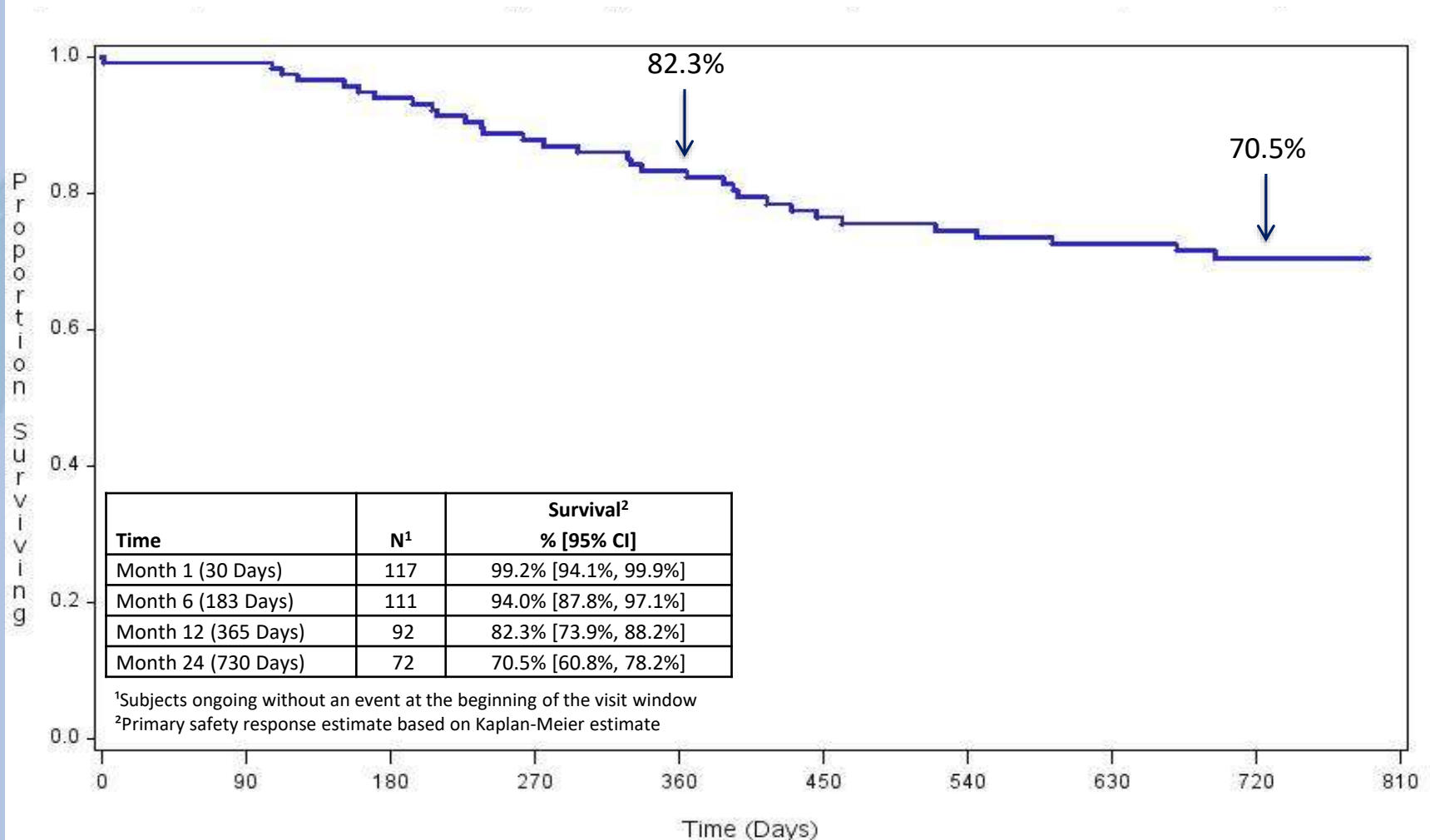
AEs CEC Adjudicated

# Demographics / Procedural Information

Description	Lutonix Long Lesion Study DCB Subjects
Age (Years), Mean $\pm$ SD (n)	67.6 $\pm$ 9.23 (118)
BMI $\geq$ 30 kg/m <sup>2</sup> (n/N)	26.3 % (30/114)
Diabetes	36.4% (43/118)
Baseline Target Limb Rutherford Grade, % (n/N)	
2	24.1% (28/116)
3	69.0% (80/116)
4	5.2% (6/116)
Baseline ABI of Target Limb, Mean $\pm$ SD (n)	0.69 $\pm$ 0.26 (111)
<b>Highest TASC Classification, % (n/N)</b>	
B	0.8% (1/118)
C	<b>77.1% (91/118)</b>
D	<b>22.0% (26/118)</b>
Total Target Lesion Length (mm), Mean $\pm$ SD (n)	212.5 $\pm$ 68.32 (117)
<b>Maximum Lesion Length (mm)</b>	<b>450mm</b>
Balloons per Subject, Mean $\pm$ SD (n) / Range	2.2 $\pm$ 0.62 (118) / (1.0, 4.0)
<b>CTO, % (n/N)</b>	<b>52.1% (61/117)</b>
RVD (mm), Mean $\pm$ SD (n)	4.7 $\pm$ 0.76 (117)
<b>Calcification, % (n/N)</b>	<b>88.1% (104/118)</b>
Severe Calcification	21.2% (22/104)



# Freedom from Primary Safety Events\*



\*Composite of freedom from all-cause peri-procedural (≤30 day) death and freedom at 1 year from the following: index limb amputation (above or below the ankle) and index limb re-intervention.

# Safety Profile Comparison to Levant 2

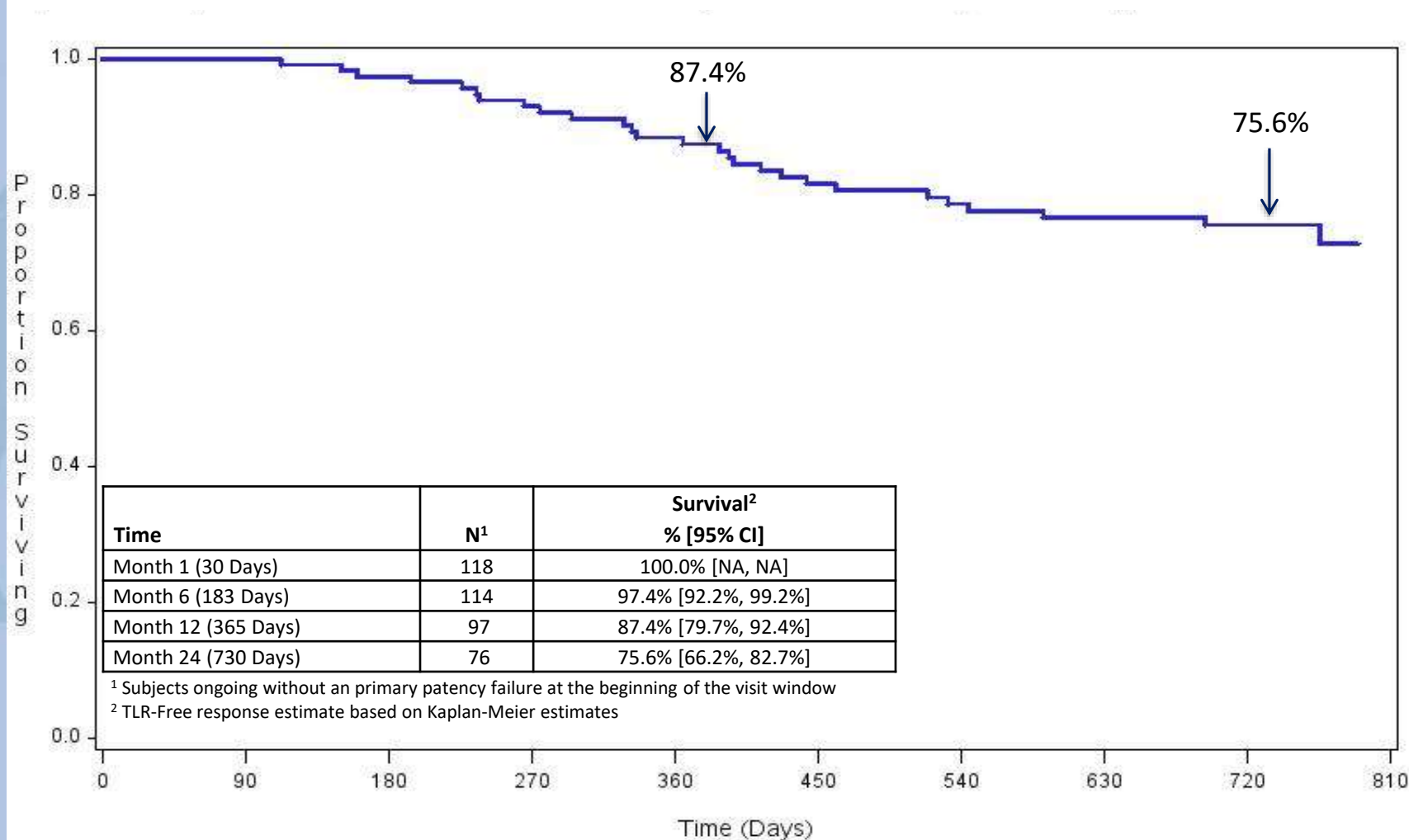
Freedom From	Long Lesion Study % (n/N)	LEVANT 2 Study DCB Subjects % (n/N)
All Cause Death	94.5% (103/109)	92.4% (257/278)
Major Amputation	98.1% (104/106)	99.6% (260/261)
Minor Amputation	98.1% (103/105)	99.6% (259/260)
TVR	73.6% (78/106)	78.5% (208/265)

Freedom From	Long Lesion Study % (n/N)	LEVANT 2 Study DCB Subjects % (n/N)
Vascular Complications 30 days	97.4% (112/115)	95.8% (295/308)

**3.5x Longer Lesions with Similar Safety Profile**

**Low 2.6% Vascular Complications Rate**

# Freedom from TLR



# Clinical Benefit Improvement

Assessment	From Baseline Improvement at 24m
Rutherford	~80% of Subjects Improved by at Least One Category >60% of Subjects Improved by at Least Two Categories
ABI	35% Improvement

# Lutonix Long Lesion vs. Zilver PTX

	Long Lesion Study	Zilver PTX
Age (Years), Mean $\pm$ SD (n)	67.6 $\pm$ 9.23 (118)	66.9 $\pm$ 9.5 (110)
Male, % (n/N)	73.7% (87/118)	74.5% (82/110)
Hypertension% (n/N)	85.6% (102/118)	82.7% (91/110)
Hypercholesteremia% (n/N)	38.1% (45/118)	62.7% (69/110)
Any Diabetes % (n/N)	36.4% (43/118)	39.1% (43/110)
Type 1	0.8% (1/118)	9.3% (4/43)
Type 2	35.6% (42/118)	90.7% (39/43)
Smoking % (n/N)	70.3% (83/118)	79.1% (87/110)
Current Smoker	41.5% (49/118)	39.1% (43/110)
Past Smoker	28.8% (34/118)	40.0% (44/110)
Renal Disease % (n/N)	27.1% (32/118)	13.6% (15/110)
Any Calcification% (n/N)	88.1% (104/118)	86.2% (100/116)
Severe Calcification	21.2% (22/104)	17.2% (20/116)

# Lutonix Long Lesion vs. Zilver PTX

Kaplan- Meier Freedom From	Long Lesion Study (Mean length 212.5±68.3mm / Range 100.0, 450.0)	Zilver PTX (Lesion length range >140-240mm)
TLR (12 months)	87.4%	75.6%
TLR (24 months)	75.6%	71.3%

**Higher Freedom from TLR!**

# Conclusions

- Complex Long Lesions:
  - Lesion Lengths Up to **450mm**
  - **88% Calcification**
    - **21% Severely Calcified**
  - **99.1% TASC C and D Lesions**
- Similar Safety Profile to Levant 2
  - **Low (2.6%) Vascular Complications Rate**
- Rutherford Category Improvement
  - ~80% of Subjects Improved by at Least One Category
  - >60% of Subjects Improved by at Least Two Categories

**Higher Freedom From TLR than Zilver PTX  
at 12 and 24 Months**

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